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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/524,612 | 05/15/2006 | Jason Gordon Beith | 207195 (8830-318) | 9867 |

7590 07/21/2008
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| EXAMINER |
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STROUD, JONATHAN R

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| ART UNIT | PAPER NUMBER |
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3774

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07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/524,612 | Applicant(s) BEITH, JASON GORDON | |
| | Examiner JONATHAN R. STROUD | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 16-23, drawn to a heart valve, classified in class 623, subclass 2.12.
 - II. Claims 24-30, drawn to a method of making a heart valve, classified in class 623, subclass 2.12.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case they could be made by a materially different process, for instance, shaping an allogenic or xenogenic piece of tissue, or not coating the devices.

4. Claims 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in a phone call on July 10, 2008.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moe 2002/0082687.

7. Moe teaches the device as claimed, namely a polymer leaflet heart valve with a base geometry, fig. 1, abstract, and three heart valve leaflets 14 supported by commissures 24. Moe further teaches that "in particular, by providing leaflets having an analytic shape in a selected position which can be represented generally by analytic geometry. An analytic shape may include a portion of a cylindrical surface, of an ellipsoid, of a paraboloid, or of another shape that can be defined mathematically."

Moe fails to teach specifically a shape defined by a parabola in the x-y direction and a parabola in the z direction.

However, it has been held that changes in size and shape, especially those previously known and defined in the art, is a design choice obvious to one of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955), In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976), 531 F.2d at 1053, 189 USPQ at 148.). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). See MPEP 2144.04 IV A-C.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Isabella David can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774
/Thomas J Sweet/
Primary Examiner, Art Unit 3774